Bressant, Janet

From: JENKINS, DANIEL J [AG/1920] <daniel.j.jenkins@monsanto.com>
Sent: Tuesday, March 24, 2015 10:24 AM
To: JENKINS, DANIEL J [AG/1920]; Goodis, Michael
Cc: Keigwin, Richard; Cyran, Carissa; Rowland, Jess; Anderson, Neil; Housenger, Jack
Subject: RE:

The German Regulators have responded. We hope that EPA would consider the following in their approach to responses:

Does Glyphosate cause cancer?
(English translation of text at http://www.bfr.bund.de/cm/343/loest-glyphosat-krebs-aus.pdf)
Communication 007/2015 BfR March 23, 2015
Glyphosate, the ingredient in plant protection products, was deemed non-carcinogenic after review by national, European and other international institutions including the Joint Meeting on Pesticide Residues of the World Health Organisation and UN Food and Agriculture Organisation, of all the studies at their disposal.
At a meeting of the International Agency for Research on Cancer (IARC) of the World Health Organization in Lyon in March 2015, experts gathered to discuss glyphosate and, based on the studies they looked at, came to a different classification, namely as a Group 2A carcinogen, or "probably" carcinogenic for humans. This Classification was published in a short report in the journal "Lancet" on March 20, 2015.
The (German) Federal Institute for Risk Assessment (BfR) was appointed EU rapporteur for glyphosate as part of the EU re-evaluation and is commenting on this IARC Classification on the basis of the summary that was published.
Seventeen experts from 11 countries met at the IARC in March 2015 to weigh the carcinogenicity or potential carcinogenicity of four organophosphates and glyphosate, none of which has been classified by the competent European authorities as carcinogenic or mutagenic.
On the basis of the information at the BfR's disposal, the classification of glyphosate in the Lancet on March 20 as belonging to Group 2A (probably carcinogenic to humans) is **scientifically hard to follow and apparently based on very few studies**. The IARC decision cannot be judged definitively, however, since the final IARC Monograph, in which its decision will be backed up with more information, is not yet published.
The recently published IARC classification is based partially on indications of carcinogenic effect in human studies, i.e. a statistical relationship between exposure to glyphosate and an increased risk of non-Hodgkin lymphomas. This risk is derived from three epidemiological studies from the USA, Canada and Sweden. However, this conclusion was not shared a very large scale "Agricultural Health Study", also cited, or by other studies. **In the current report of the BfR to the EU, on the other hand, over 30 epidemiological studies were evaluated. In the comprehensive opinion, there was no proven relationship between exposure to glyphosate and an increased risk of non-Hodgkin's lymphoma or other types of cancer.**
Furthermore, IARC advances findings from animal testing as proof of a carcinogenic effect of glyphosate. All of these findings were also considered in the glyphosate appraisals of the BfR, the EU institutions and the Joint Meeting on Pesticide Residues of the WHO and FAO, which is responsible for the appraisal of pesticide ingredients. These organizations came to the overall conclusion that glyphosate is not carcinogenic. The BfR does not know how many of the 11 long-term studies on rats and mice considered valid by the BfR were available to the IARC.
The theory advanced in one study that skin tumors could be caused by a highly concentrated, irritant formulation with the ingredient were also not regarded by the EU institutions as proof for the carcinogenic qualities of glyphosate.
Indications for a gene toxic potential of glyphosate cannot be concluded from IARC's published summary, since the review also included formulations that were not further described.

The fact that different bodies reach different conclusions from different information and interpretations of experimental data is a daily reality in risk assessment. The BfR will examine IARC'sclassification in detail once the Monograph is published.

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From: JENKINS, DANIEL J [AG/1920]
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Subject:

Mike:

Per our phone conversation. We hope EPA will correct mistakes or absences of fact with respect to its record on glyphosate (including the 2013 statement and the AHS study) as it relates to carcinogenicity.

> **2009 EPA Glyphosate Reg Review**
> Carcinogenicity was not identified as a concern in the work plan
> **http://www.epa.gov/oppsrrd1/registration_review/glyphosate/**
>
> **2013 Federal Register Notice (FR 25396 Vol. 78, No. 84, Wednesday, May 1, 2013)** Final Rule new tolerances in or on multiple commodities: "EPA has concluded that glyphosate does not pose a cancer risk to humans."
> **http://www.gpo.gov/fdsys/pkg/FR-2013-05-01/pdf/2013-10316.pdf**

"For the herbicide **glyphosate**, there was *limited evidence of carcinogenicity* in humans for non-Hodgkin lymphoma. The evidence in humans is from studies of exposures, mostly agricultural, in the USA, Canada, and Sweden published since 2001. In addition, there is convincing evidence that glyphosate also can cause cancer in laboratory animals. On the basis of tumours in mice, the United States Environmental Protection Agency (US EPA) originally classified glyphosate as *possibly carcinogenic to humans* (Group C) in 1985. After a re-evaluation of that mouse study, the US EPA changed its classification to *evidence of non-carcinogenicity in humans* (Group E) in 1991. The US EPA Scientific Advisory Panel noted that the re-evaluated glyphosate results were still significant using two statistical tests recommended in the IARC Preamble. The IARC Working Group that conducted the evaluation considered the significant findings from the US EPA report and several more recent positive results in concluding that there is *sufficient evidence of carcinogenicity* in experimental animals. Glyphosate also caused DNA and chromosomal damage in human cells, although it gave

negative results in tests using bacteria. One study in community residents reported increases in blood markers of chromosomal damage (micronuclei) after glyphosate formulations were sprayed nearby."

http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)70134-8/abstract

http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf

Thanks,

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